F304 - APPLICATION FOR ACCREDITATION: ISO GUIDE 34 REFERENCE MATERIAL PRODUCERS

Introduction

The *A2LA Accreditation Program for Reference Material Producers* is designed for producers of reference materials who wish to demonstrate their competence by formal compliance with a set of internationally recognized criteria. The program will also provide users of reference material, such as testing and calibration laboratories, with increased confidence that the reference material being relied upon are being produced in accordance with specified technical and management system requirements and are of appropriate quality.

The requirements for this program are listed in ***C307 – General Checklist: ISO Guide 34 Reference Material Producer Accreditation Program*** and are based on those contained in ISO Guide 34:2000, "***General Requirements for the Competence of Reference Material Producers***." ISO Guide 34 sets out the general requirements in accordance with which a reference material producer has to demonstrate that it operates, if it is to be recognized as competent to carry out the production of reference material. It is recognized that each reference material needs to be characterized mainly to the level of accuracy required for its intended purpose (i.e. appropriate measurement uncertainty.)

It should also be noted that ISO Guide 34 requires compliance with ISO Guide 30:1992 (***Terms and Definitions Used in Connection with Reference Materials***), ISO Guide 31: 2000 (***Contents of Certificates of Reference Materials***), and ISO Guide 35:2006 (***Certification of Reference Materials – General and Statistical Principles.)***

Application Documents

The full application package includes the following four documents:

(1) This ***Application Form.***

(2) ***F305 – Scope of Accreditation Selection List: ISO Guide 34 Reference Material Producers.***

(3) ***R304 – General Requirements: Accreditation of ISO Guide 34 Reference Material Producers***.

(4) ***C307 – General Checklist: ISO Guide 34 Reference Material Producer Accreditation Program***.

If you do not have all four of these documents, please contact A2LA Headquarters to obtain them.

ACCREDITATION PROGRAM FOR REFERENCE MATERIAL PRODUCERS

Application Form Index

Typical Steps in the Accreditation Process

1. The applicant reference material producer completes and returns this application for accreditation with payment.

2. A2LA reviews the application documents for completeness and develops the DRAFT "Scope of Accreditation" based on the information provided by the applicant. Appropriate assessor(s) are then assigned, with the reference material producer's concurrence.

3. Once documentation is reviewed for compliance, the assessment can be scheduled with the assessor(s). Note that the assessor(s) may take into account recent assessment or audit reports from other recognized accreditation bodies or registrars with the intent of reducing, wherever possible, duplication in the assessment process and the length of time it takes to complete the assessment.

4. The assessment or the pre-assessment is performed and includes, where applicable: entry briefing; review of quality documentation, records, reports, interviews with staff, written report of assessor's findings, and exit briefing. The scope of the assessment is limited to the specific categories of reference materials for which the reference material producer is seeking accreditation.

5. The reference material producer responds to any deficiencies with a written corrective action response within 30 days.

6. The corrective action response is reviewed by A2LA staff. Once all deficiencies have been resolved, the reference material producer's assessment package is forwarded to the Accreditation Council for a vote.

7. Accreditation is granted when affirmative votes are received from the Accreditation Council members, all concerns are resolved, and all fees are paid in full.

8. Accreditation is granted for a two-year period. An on-site surveillance assessment is conducted at the mid-point of the first two-year accreditation period. Full renewal assessments are then conducted every two years, with an Annual Review taking place at the mid-points of those two-year periods, unless it is determined that an on-site surveillance is warranted.

ACCREDITATION PROGRAM FOR REFERENCE MATERIAL PRODUCERS

POLICIES

Confidentiality Policy: A2LA is responsible for seeing that confidentiality is maintained by its employees and assessors concerning all confidential information with which they become acquainted as a result of their contacts with reference material producers. The Association agrees to hold all disclosed confidential or proprietary information or trade secrets in trust and confidence. The information shall be used only for assessment purposes, and shall not be used for any other purpose, nor shall it be disclosed to any third party without written consent of the applicant reference material producer.

Refund Policy: If a reference material producer withdraws the application before completion of the assessment, it may apply for a refund of up to 50% of the initial application and annual fees and the balance of the unexpended assessor deposit. There will be no refund of annual fees after the assessment has been completed. Refunds of any balance remaining on the assessor deposit will be made at the time of the accreditation decision. Any withdrawal or refund request must be made in writing. Note: Fees in future years are subject to change

Delayed Assessment Policy: If a reference material producer fails to undergo its full assessment within one year from receipt of the application at A2LA headquarters, the reference material producer is prompted by A2LA to take action. If no action is taken within thirty (30) days of that reminder, the reference material producer is required to begin the application process again and pay the new reference material producer accreditation fees in effect at that time. Any fees paid with the initial application are refunded according to the A2LA Refund Policy (see above).

Pre-assessment Policy: A2LA assessors are permitted to conduct pre-assessments. There are two situations when a pre-assessment may be conducted:

1. When the lead assessor finds major gaps in the reference material producer's quality manual, or actually begins the assessment and finds a large number of problems. In this case, the assessor identifies them and suggests to the reference material producer that a full assessment should wait until the problems have been addressed. This first identification of the problems would be considered a pre-assessment.

2. When a reference material producer requests a pre-assessment to better prepare for the final assessment. In this case, the reference material producer has applied, but is unsure of its documentation or system and wants someone to perform a pre-assessment to identify areas of non-compliance. The full assessment follows later. Note that in the case of a pre-assessment, the assessor cannot consult with the reference material producer on resolution of any identified non-compliance(s). The assessor can only point out gaps and/or omissions in the quality system.

To implement the pre-assessment program, the reference material producer must first apply for accreditation, paying the appropriate fees and assessor deposit. A lead assessor is assigned, with the reference material producer's concurrence. If, during the discussions between the reference material producer and assessor in preparation for the assessment, the reference material producer concludes that it is in its interest to have a pre-assessment, it informs the assessor. The assessor notifies A2LA that the reference material producer wants a pre-assessment. The cost of the pre-assessment is not included in the estimated cost of the assessment. A2LA bills the reference material producer after the pre-assessment for any additional costs incurred that are not covered by the amount of assessor deposit submitted with the initial application. The assessor does not prepare a formal report of findings, but keeps notes that are reviewed during the final assessment. Careful attention to the requirements should preclude the need for a pre-assessment.

ACCREDITATION PROGRAM FOR REFERENCE MATERIAL PRODUCERS

APPLICANT INFORMATION SHEET

REFERENCE MATERIAL PRODUCER NAME AND ADDRESS (as you wish it to appear on a certificate of accreditation and in the A2LA Directory)

1. Reference Material Producer Name: _____

_____

2. Street Address:

_____

_____

_____

3. Mailing Address: (if different)

_____

_____

_____

4. GENERAL DESCRIPTION OF THE TYPES OF REFERENCE MATERIAL CATEGORIES TO BE INCLUDED IN THE ACCREDITATION: (Please Complete Selection List).

_____

_____

5. Number of personnel at this location, associated with the reference material producer's programs to be included in the accreditation : _____.

6. Check one of the following as it applies to your reference material production. This information is for reference by A2LA in response to inquiries.

- ☐ Commercial service provided
- ☐ Commercial services provided on a conditional basis
- ☐ No commercial service provided.

AUTHORIZED REPRESENTATIVE of the reference material producer who is the contact person responsible for the information provided in this application and for ensuring compliance with the requirements for A2LA accreditation.

_____	_____	(_____)_____ - _____
Signature	Title	Telephone Number
_____	_____	(_____)_____ - _____
Printed Name	Date	FAX Number

E-mail Address: _____

For A2LA office use only: MC #: _____Assessment #:_____

ACCREDITATION PROGRAM FOR REFERENCE MATERIAL PRODUCERS

DRAFT SCOPE OF ACCREDITATION

Please complete this chart for all programs for which accreditation is being sought **and attach any relevant material information** normally sent to recipients of the reference materials. Please refer to ***F305 – Scope of Accreditation Selection List: ISO Guide 34 Reference Material Producers*** for the list of reference material categories[1]. Please separate materials that can be classified as Certified Reference Materials (i.e. those for which traceability to the SI unit can be demonstrated) from those which can be assigned to Reference Materials only (for which full traceability cannot be demonstrated).

Category and Sub-category of Reference Material	**Test, Analysis, Measurement** (including ranges and uncertainties)	**Method**	**Measurement Technique** (where appropriate)
Examples:			
Certified Reference Materials			
Category D4.1 Rockwell Hardness	HRC: > 60 HRC Best Uncertainty – 0.32 HRC (40 to 59) HRC Best Uncertainty – 0.33 HRC (20 to 39) HRC Best Uncertainty – 0.39 HRC	ASTM E18	
Reference Materials			
Category A3.3 Foodstuffs – Trace elements in bovine liver (freeze-dried)	Lead Range 0.05 – 03 mg/kg Uncertainty: ± 0.01 mg/kg Cadmium Range 0.10 – 0.90 mg/kg Uncertainty: ± 0.02 mg/kg	AOAC	ICP/AES

Note 1) Categories derived from ILAC-G12:2000 Appendix B

For A2LA office use only: MC #: _____ Assessment #:_____

ACCREDITATION PROGRAM FOR REFERENCE MATERIAL PRODUCERS

COLLABORATOR (SUB-CONTRACTOR) INFORMATION

Please complete this chart for all collaborators (sub-contractors) with which the reference material producer has formal arrangements for the production, testing, measurement, sampling, storage, assignment of property values, and distribution of reference materials. *(Note: A collaborator (sub-contractor) is a technically competent body (organization or firm, public or private) that undertakes aspects of the manufacture, or characterization, of the reference material on behalf of the reference material producer, either on a contractual or voluntary basis.)*

Name	**Address & phone number**	**Description of activity/service rendered**

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ACCREDITATION PROGRAM FOR
REFERENCE MATERIAL PRODUCERS

SUPPORTING INFORMATION SHEET

1. Attach an up-to-date reference material producer organization chart and identify **by name**, the personnel involved for each function related to the **production of the reference materials and assignment of property values of the reference materials produced.**

2. If the Reference material producer is part of a larger organization, attach a chart of its position and reporting relationships within that organization.

3. Attach a list of all the equipment dedicated to the handling, sampling, analysis, storage, etc. of reference materials for which the reference material producer is seeking accreditation. Details should include make, model, serial number, range, and calibration status (date of last calibration/check, name of calibration service used) if applicable, and the time intervals between calibrations or checks. Preferred order for the list is (a) reference equipment, (b) major testing equipment, (c) ancillary equipment.

4. Attach a representative sample of the Certificates of Analysis that accompany the reference materials of the type for which accreditation of production is being sought.

5. Obtain a copy of ***C307 – General Checklist: ISO Guide 34 Reference Material Producer Accreditation Program*** from A2LA, complete and return it with your completed application forms.

6. Please include an uncontrolled copy of the current version of your quality manual and any supporting documentation referenced in the assessor checklist(s) i.e. operating procedures and work instructions. Submitting your quality manual and supporting documentation via email or electronically on disc is preferred.

7. The A2LA Confidentiality Policy (***R304 – General Requirements: Accreditation of ISO Guide 34 Reference Material Producers,*** Part A, Section XIV) states that all information regarding your application is confidential. To maintain confidentiality regarding an applicant's status, A2LA staff will only confirm whether a laboratory is or is not accredited. If you would like to waive this policy and allow A2LA staff to confirm in response to inquiries that your laboratory has applied and is in the accreditation process, please provide the required written permission below.

   _____ I authorize A2LA to release information regarding our application status.
   INITIAL/DATE

   _____ I do not authorize A2LA to release information regarding our application status.
   INITIAL/DATE

8. Please indicate your reason(s) for pursuing accreditation with A2LA (answering is optional):

_____

_____

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ACCREDITATION PROGRAM FOR REFERENCE MATERIAL PRODUCERS

CONDITIONS FOR ACCREDITATION

To attain and maintain accreditation, an applicant must agree to:

1) Cooperate as necessary to enable A2LA to verify compliance with the requirements for accreditation, including provision for examination of documentation and access to all areas, equipment, records and personnel for the purposes of assessment, surveillance, reassessment and resolution of complaints;
2) Comply at all times with the ***Requirements***, and these conditions for accreditation;
3) Claim that it is accredited only with respect to services for which it has been granted accreditation and which are carried out in accordance with these conditions;
4) Pay such fees as shall be determined by A2LA within the times specified;
5) Retain all quality records (as defined in ISO Guide 34 4.11.1a) and technical records supporting (as defined in ISO Guide 34 4.11.1b) throughout the period between A2LA on-site assessments bearing in mind that adequate records must be available to demonstrate full compliance with the requirements for accreditation;
6) Upon request, provide A2LA with copies of the results of reliability monitoring programs (both internal and external) used to verify the testing and characterization of reference materials and to determine the uncertainty of property values assigned to the analytes and characteristics in those materials.
7) Not use its accreditation in such a manner as to bring A2LA into disrepute and not make any statement relevant to its accreditation which A2LA may consider misleading or unauthorized;
8) Upon suspension, withdrawal or expiration of its accreditation (however determined) discontinue its use of all advertising matter that contains reference thereto and return any certificates of accreditation to A2LA;
9) Not use its accreditation to imply product approval by A2LA;
10) Endeavor to ensure that no certificate or report, nor any part thereof, is used in a misleading manner;
11) Comply with the requirements of A2LA in making reference to its accreditation status in communication media such as advertising, brochures or other documents;
12) Inform A2LA headquarters, within 30 days and in writing of changes or pending changes in any aspect of the reference material producer's status or operation that affect the reference material producer's legal, commercial or organizational status; organization or management (e.g., managerial staff); policies or procedures, where appropriate; premises; personnel, equipment, facilities, working environment or other resources, where significant; authorized signatories; or such other matters that may affect the reference material producer's capability, or scope of accredited activities, or compliance with the criteria, requirements and conditions for accreditation;
13) Carry out any adjustments to its procedures in response to due notice of any intended changes by A2LA to the criteria, requirements, or conditions for accreditation, in such time as in the opinion of A2LA is reasonable.

The accredited reference material producer's AUTHORIZED REPRESENTATIVE[1] is responsible for ensuring that all of the relevant conditions for accreditation are met. As the applicant reference material producer's AUTHORIZED REPRESENTATIVE, I agree to the above conditions for accreditation. I attest that all statements made on this application are correct to the best of my knowledge and belief.

SIGNATURE _____ DATE: _____

PRINTED NAME _____ TITLE: _____

For A2LA office use only: MC #: _____ Assessment #:_____

[1]An Authorized Representative is: an official who represents the reference material producer in all matters related to attaining and maintaining A2LA accreditation. This official is A2LA's point of contact with the reference material producer. The Authorized Representative may be any senior person in the reference materials producer's organization from either the technical or managerial staff. He or she should be in a position of authority to ensure that the reference material supplier complies with the A2LA criteria and conditions for accreditation.

ACCREDITATION PROGRAM FOR
REFERENCE MATERIAL PRODUCERS ACCREDITATION
DESCRIPTION OF FEES

Initial Application Fee ($ 600.00) - One time fee for all new applicant reference material producers. This fee is waived if the applicant is already accredited with A2LA under another program such as laboratory accreditation.

Annual Review Fee ($ 1,200.00) - Accreditation is granted for two years. The Annual Review Fee is required to continue accreditation after the first year of accreditation. This fee is reduced to $ 1,000.00 if the applicant is already accredited with A2LA under another program such as laboratory accreditation. Reference material producers are required to submit updated information on their organization, facilities, and reference materials produced. Objective evidence of completion of the internal audit and management review is also required.

Assessment Fee (actual cost of assessment) - A2LA requires an initial Assessor Deposit of **$ 2,000.00 per assessor** towards the actual costs of the assessment. These actual costs can vary significantly depending upon a reference material producer's size, desired scope of accreditation, and adequacy of its preparation for the assessment. Assessors can provide cost estimates before the visit and will leave a written estimate of actual assessment costs upon departure. After the assessment takes place, you will be billed (or refunded) the difference between the actual costs and the Assessor Deposit. Actual costs are computed based on:

- Total Assessment Time[2] at $ 1,080 per 8-hour day;
- Travel (airfare, rental car, or private auto @ IRS allowable rate); and
- Accommodations & Miscellaneous (hotel, meals, parking, calls, etc.)

A full renewal assessment is conducted every two years. If there are substantial changes in operations or concerns about the reference material producer's performance, reassessment at actual cost may be required sooner than the normal two-year interval. Additional reference material categories may be added to a Reference material producer's scope of accreditation at any time, but may result in the need for an interim on-site assessment.

Surveillance Assessment (actual cost of the assessment) – A2LA requires that all newly accredited reference material producers undergo an on-site surveillance visit at the mid-point of the **first** 2-year accreditation, period. This surveillance is normally limited to one-day on-site. Future surveillance visits are only arranged when deemed necessary.

TO INITIATE THE ACCREDITATION PROCESS, PLEASE SUBMIT THE FOLLOWING FEES:

Initial Application Fee (new reference material producer in the system, first year only) *Note: This fee is waived if the applicant is already accredited with A2LA under another program such as laboratory accreditation.*	$ 600
Annual Fee *Note: This fee is $ 1,000 if the applicant is already accredited with A2LA under another program such as laboratory accreditation.*	$ 1,200
Assessor Deposit (for each assessor) *Note 1: Depending on the number and technical nature of reference materials being produced, additional assessors may be necessary. Once your application is reviewed at A2LA Headquarters, you will be notified if additional assessors will be assigned.* Note 2: *The reference material producer will be billed or refunded the difference between actual cost and the assessor deposits paid. Accreditation will not be granted until all fees are paid.*	$ 2,000
TOTAL (to be submitted with application) *Note: Total is **$ 3,000** ($ 1,000 Annual Fee + $ 2,000 Assessor Deposit) for applicants already accredited by A2LA under another program such as laboratory accreditation.*	**$ 3,800.00**

[2] Assessment Time. An assessment of one reference material producer ~~supplier~~ can take from 1 to 4 days, with additional time taken for preparation and report writing. If travel takes more than two hours, an additional cost at one half the assessment rate will be added for each additional hour. It is to the RM producer's advantage to be prepared and to help prepare the assessors beforehand. If the quality system documentation is not sent to assessors beforehand, assessors will need additional time at the RM producer. If the scope of accreditation changes significantly as the assessment progresses, assessors will also need more time. If there are significant deficiencies, assessor follow-up time may be charged. A2LA audits the expenses and pays assessors. Do not pay assessors directly. Do check the assessor's written estimate of assessment costs.

ACCREDITATION PROGRAM FOR
REFERENCE MATERIAL PRODUCERS
APPLICATION CHECKLIST

Please use this checklist to review your application package prior to submitting it to A2LA. Completion of the required items is necessary for the efficient processing of your application. Delays may occur if additional or clarifying information is needed. Before mailing your application to A2LA, have you done the following:

- ❑ Identified your reference material producer's Authorized Representative?
- ❑ Completed the APPLICANT INFORMATION Sheet (page 4)?
- ❑ Completed the DRAFT SCOPE OF ACCREDITATION sheet (page 5) and attached relevant brochures?
- ❑ Completed the COLLABORATOR (SUB-CONTRACTOR) INFORMATION sheet (page 6)
- ❑ Completed the SUPPORTING INFORMATION sheet (page 7) and attached organizational charts, equipment list, and samples of certificates of analysis?
- ❑ Read, understood and signed the CONDITIONS FOR ACCREDITATION OF REFERENCE MATERIAL PRODUCERS (page 8)?
- ❑ Reviewed the DESCRIPTION OF FEES sheet (page 9) and submitted a check made payable to "A2LA" in US$ for the appropriate amount, $ 3,800.00 (or $ 3,000 if the applicant is already accredited by A2LA under another program)? An application cannot be considered until payment, or an arrangement for payment, is made.
- ❑ Read ***R304 – General Requirements: Accreditation of ISO Guide 34 Reference Material Producers*** to ensure a basic understanding of the accreditation process?
- ❑ Completed the attached ***C307 – General Checklist: ISO Guide 34 Reference Material Producer Accreditation Program*** in accordance with the instructions provided and submit a copy to A2LA.
- ❑ Return to A2LA the following pages: this checklist page, and pages 4, 5, 6, 7, 8, of the Application, all attachments in response to any question in this application, the completed ***C307 – General Checklist: ISO Guide 34 Reference Material Producer Accreditation Program***, and a check in the appropriate amount, to A2LA at the address below**.**

Completed by (Name): _____Date: _____

For A2LA office use only: MC #: _____ Assessment #: _____